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## **Effectiveness of the Gold Standard Programme compared with other smoking cessation interventions in Denmark**

### **A cohort study**

Rasmussen, Mette; Fernández, Esteve; Tønnesen, Hanne

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# BMJ Open Effectiveness of the Gold Standard Programme compared with other smoking cessation interventions in Denmark: a cohort study

Mette Rasmussen,<sup>1</sup> Esteve Fernández,<sup>2,3</sup> Hanne Tønnesen<sup>4,5</sup>

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For numbered affiliations see end of article.

**Correspondence to**  
Mette Rasmussen;  
[mette.rasmussen.03@regionh.dk](mailto:mette.rasmussen.03@regionh.dk)

## ABSTRACT

**Objectives:** We compared the effectiveness of the Gold Standard Programme (a comprehensive smoking cessation intervention commonly used in Denmark) with other face-to-face smoking cessation programmes in Denmark after implementation in real life, and we identified factors associated with successful quitting.

**Design:** Prospective cohort study.

**Setting:** A total of 423 smoking cessation clinics from different settings reported data from 2001 to 2013.

**Participants:** In total, 82 515 patients were registered. Smokers  $\geq 15$  years old and attending a programme with planned follow-up were included. Smokers who did not want further contact, who intentionally were not followed up or who lacked information about the intervention they received were excluded. A total of 46 287 smokers were included.

**Interventions:** Various real-life smoking cessation interventions were identified and compared: The Gold Standard Programme, Come & Quit, crash courses, health promotion counselling (brief intervention) and other interventions.

**Main outcome:** Self-reported continuous abstinence for 6 months.

**Results:** Overall, 33% (11 184) were continuously abstinent after 6 months; this value was 24% when non-respondents were considered smokers. The follow-up rate was 74%. Women were less likely to remain abstinent, OR 0.83 (CI 0.79 to 0.87). Short interventions were more effective among men. After adjusting for confounders, the Gold Standard Programme was the only intervention with significant results across sex, increasing the odds of abstinence by 69% for men and 31% for women. In particular, compliance, and to a lesser degree, mild smoking, older age and not being disadvantaged were associated with positive outcomes for both sexes. Compliance increased the odds of abstinence more than 3.5-fold.

**Conclusions:** Over time, Danish smoking cessation interventions have been effective in real life. Compliance is the main predictor of successful quitting. Interestingly, short programmes seem to have relatively strong effects among men, but the absolute numbers are very small. Only the comprehensive Gold Standard Programme works across sexes.

## Strengths and limitations of this study

- This study was based on a large cohort of smokers from all regions and settings in Denmark; 46 287 smokers were included in the study, and the follow-up rate was high (74%).
- The study was based on routinely collected health data with high completeness and precision, and the implications were considered minimal, as the research question was in line with the purposes of the database.
- Confounding effects were carefully considered and adjusted for, but we cannot exclude the possibility of residual confounding from other potential confounders, such as genetic predispositions, comorbidities, competing addictions and lifestyle factors not considered due to a lack of information.
- A limitation is that the results were based on self-reporting since patients are likely to overestimate their success; we assumed that overestimations were evenly distributed and that the groups were thus comparable in spite of potentially slightly overestimated quit rates.
- Owing to varying cultural traditions, smoking habits and socioeconomic conditions, generalisations should be considered carefully.

## INTRODUCTION

Tobacco is the most damaging and preventable lifestyle factor affecting public health globally and nationally.<sup>1 2</sup> Its harmful effects are well documented.<sup>3</sup> Globally, the WHO estimates that ~6 million people die from smoking-related diseases yearly.<sup>1</sup> Many countries, including Denmark, have introduced restrictive laws and strategies to reduce smoking.<sup>4</sup> More than 12 800 people in Denmark die as a consequence of smoking annually, corresponding to 1 in 4 deaths.<sup>4</sup>

Over the past 15–20 years, many initiatives have been launched to help smokers quit. Smoking cessation programmes are one of many initiatives. Additionally, tobacco control

and policy measures have been implemented, including smoking bans, higher tobacco taxes, and restrictions on tobacco sales and advertising. Recently, Denmark signed on to the WHO's goal to reduce smoking by 30% by 2025,<sup>5</sup> and specific regions are working towards implementing a tobacco endgame.<sup>6</sup> Furthermore, there are many other resources to help smokers quit, such as a quit line, national campaigns, training materials and recently, aid based on information technology tools. These efforts have contributed to an overall change in smoking climates and attitudes. In Denmark, smoking prevalence has declined by 0.5–1 percentage point per annum during the past decade. In 2013, 17% of the Danish population over 15 years of age smoked daily, and an additional 6% smoked occasionally.<sup>7</sup>

Since 1995, the Gold Standard Programme (GSP) has become routine in Denmark, and the vast majority of smoking cessation interventions offered are the GSP.<sup>8</sup> It is a comprehensive intervention comprising five meetings over 6 weeks and fulfilling intensive clinical intervention requirements.<sup>9</sup> Programme counsellors are specially trained to provide this manual-based patient education programme. Smokers are either referred to the intervention by health practitioners, or they can contact programme providers themselves. The GSP has proven to be highly effective and cost-effective, even across subgroups,<sup>10–15</sup> but its effectiveness has not yet been compared with that of other programmes. In addition to the GSP, other face-to-face methods (eg, crash courses, health promotion counselling, alternative treatments and Come & Quit programmes) have been used and evaluated through the national Danish Smoking Cessation Database (SCDB). The aim of this study was to compare the effectiveness of the GSP with the effectiveness of other face-to-face smoking cessation programmes used in Denmark. The main hypothesis was that the GSP would be the most effective intervention after 6 months. We also aimed to identify factors associated with successful smoking cessation.

## METHODS

### Study design

This prospective cohort study on the SCDB included patients treated from 2001 to 2013 with follow-up until 2014. The SCDB lists ~80–90% of all clinics performing face-to-face interventions used in Denmark,<sup>16</sup> and we thus consider this a representative sample.

### Setting

During the study, 423 smoking cessation clinics reported data from municipal clinics, pharmacies, hospitals, midwives, primary care facilities and other private providers. Smokers could attend smoking cessation interventions free of charge with or without referrals. Approximately 10% attended an intervention at a private provider with payment. From 2001 to 2005, this proportion was 19%,

and from 2006 to 2012, it was 4%, likely due to structural changes made in the Danish healthcare system.<sup>16</sup>

### Intervention

Different real-life smoking cessation interventions were identified and compared with the data registered in the SCDB (figure 1).

In accordance with the guidelines, patients who attended at least 75% of the scheduled meetings were considered compliant.<sup>17</sup> For Come & Quit<sup>18</sup> (figure 1), four meetings corresponded to 75% of the GSP.<sup>8</sup>

### Participants

In 2001–2013, 82 515 smokers were registered in the SCDB after providing informed consent (see figure 2).

*Inclusion criteria:* Patients ≥15 years old at the beginning of the programme who attended a smoking cessation programme with planned follow-up.

*Exclusion criteria:* Patients <15 years; patients not wanting to be contacted after 6 months; patients who were intentionally not followed up because the smoking cessation clinic decided beforehand not to; and patients without information on which intervention they received.

In total, 46 287 smokers who were followed up for 6 months were included (figure 2). Of them, 26% were lost to follow-up because they did not respond or because their smoking status was missing. The remaining 34 235 patients were included in the outcome analyses. Overall, 82 387 patients were included in the non-respondent analyses.

### Data

We used data from the SCDB.<sup>8</sup> The database was established in 2000 as a research database. The SCDB is available to all providers of smoking cessation intervention, and it is free of charge. Data are reported to the SCDB using standardised questionnaires on smoking histories, sociodemographic characteristics, treatments and follow-up.

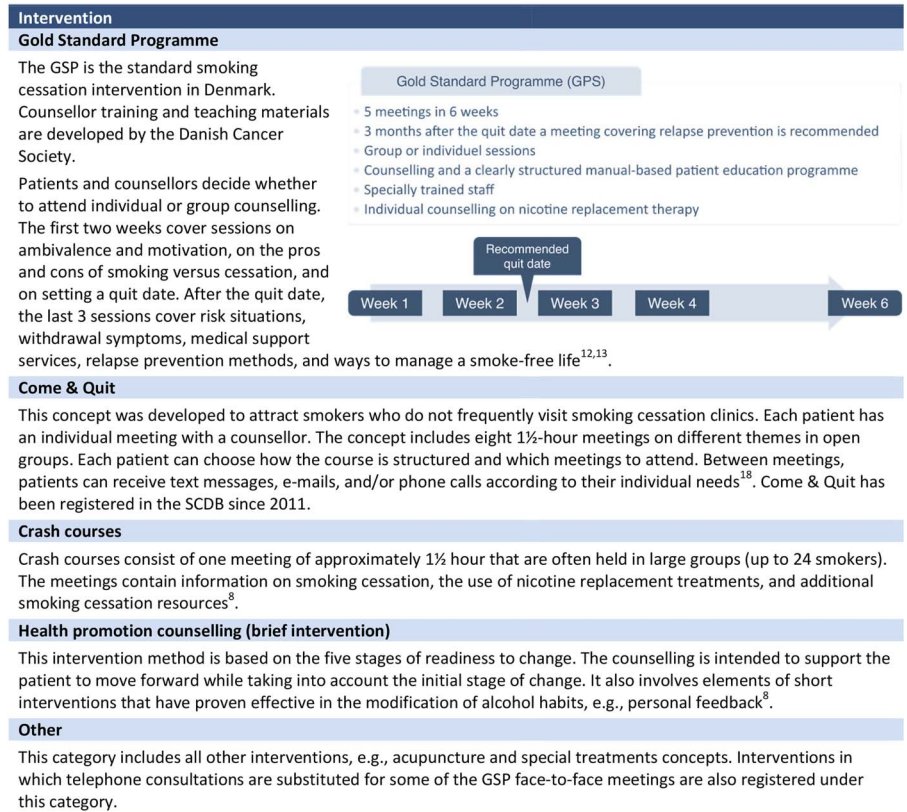
Beginning in 2006, minor adjustments were made to the questionnaires and follow-up procedures. No validation of self-reported smoking status was required.<sup>8</sup> Follow-up was 6 months after the scheduled quit date or, secondarily, the date of course completion. From 2001 to 2005, the information was collected by mail or telephone, and at least one reminder was required. For 2006 and later, the data were collected by telephone exclusively. After four attempts to reach the patient, of which at least one was made in the evening, the patient was reported as a non-respondent.

### Outcomes

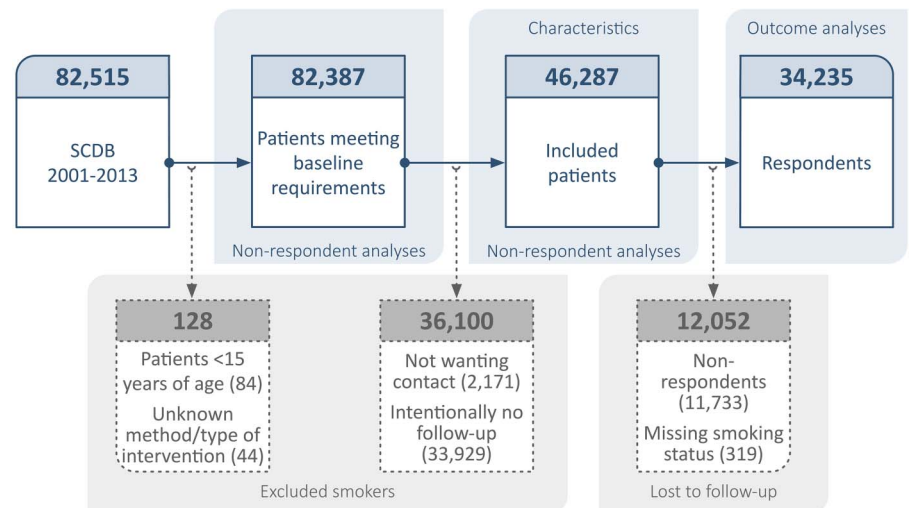
#### Primary outcome

Continuous abstinence for 6 months, defined as not smoking from the intended quit date (or previous treatment date) to the 6-month follow-up ±1 month.

**Figure 1** Descriptions of smoking cessation interventions examined in this study. GSP, Gold Standard Programme; SCDB, Smoking Cessation Database.



**Figure 2** Flow chart. In total, 82 515 smokers were registered in the SCDB and 36 228 were excluded, leaving 46 287 smokers in the study population. Of them, 26% of the study population were lost to follow-up, leaving 34 235 smokers included in the outcome analyses. SCDB, Smoking Cessation Database.



### Other variables

Factors associated with a positive outcome were studied after controlling for interventions, the time of collection, age, disadvantaged patients, heavy smoking, compliance, living with a smoker, setting, geographic region, programme format and medication offered for free.

Most variables were collected in categories. Age, daily tobacco consumption data (grams/day) and Fagerström scores on nicotine dependency (from 0 to 10 points)<sup>19</sup> were collected as continuous data. The data were categorised as shown in [table 1](#).

Data on GPS and other interventions were available throughout the study period, but data on crash courses

were only provided before 2006. Finally, Come & Quit data were recorded from 2011.

A low education level was defined as no education except primary school or short work-related courses.<sup>13</sup> Unemployment meant without a job, on sick leave or receiving compensation (in contrast to everyone else, including employees, students/patients under education, retirees and parents on maternity/paternity leave).<sup>13</sup>

Patients were defined as disadvantaged if they had been unemployed or had a low level of education.<sup>13</sup> Heavy smokers were defined as follows:  $\geq 20$  pack-years, smoking  $\geq 20$  g of tobacco/day or reaching  $\geq 7$  points on the Fagerström score.<sup>12 19</sup>



**Table 1** Characteristics of the 46 287 included smokers by intervention type

	<b>GSP n (%)</b>	<b>Health promotion counselling n (%)</b>	<b>Crash courses n (%)</b>	<b>Come &amp; Quit n (%)</b>	<b>Other n (%)</b>
Total*	40 651 (100)	140 (100)	183 (100)	1592 (100)	3721 (100)
Time for data collection					
2001	1341 (3.3)	—	37 (20.2)	—	172 (4.6)
2002–2003	6221 (15.3)	—	109 (59.6)	—	814 (21.9)
2004–2005	7933 (19.5)	—	37 (20.2)	—	529 (14.2)
2006–2007	7747 (19.1)	1 (0.7)	—	—	415 (11.2)
2008–2009	8062 (19.8)	42 (30.0)	—	—	618 (16.6)
2010–2011	5772 (14.2)	46 (32.9)	—	211 (13.3)	550 (14.8)
2012–2013	3575 (8.8)	51 (36.4)	—	1381 (86.8)	623 (16.7)
Participants					
Sex					
Men	15 655 (38.5)	71 (50.7)	75 (41.0)	638 (40.1)	1532 (41.2)
Women	24 992 (61.5)	69 (49.3)	108 (59.0)	954 (59.9)	2186 (58.8)
Age (years)					
15–24 years	1892 (4.7)	7 (5.0)	6 (3.3)	118 (7.4)	335 (9.0)
25–34 years	5173 (12.7)	25 (17.9)	24 (13.1)	140 (8.8)	523 (14.1)
35–44 years	8471 (20.8)	28 (20.0)	34 (18.6)	225 (14.1)	772 (20.8)
45–54 years	10 985 (27.0)	19 (13.6)	51 (27.9)	395 (24.8)	860 (23.1)
55+ years	14 031 (34.5)	61 (43.6)	68 (37.2)	714 (44.9)	1213 (32.6)
Education					
Low level	20 764 (51.1)	40 (28.6)	168 (91.8)	521 (32.7)	2084 (56.0)
High level	18 425 (45.3)	96 (68.6)	12 (6.6)	1024 (64.3)	1429 (38.4)
Employment					
Unemployed	6885 (16.9)	32 (22.9)	31 (16.9)	522 (32.8)	830 (22.3)
Not unemployed	32 750 (80.6)	106 (75.7)	146 (79.8)	1035 (65.0)	2779 (74.7)
Disadvantaged smokers (by work situation and education)					
Yes	23 654 (58.2)	55 (39.3)	172 (94.0)	825 (51.8)	2417 (65.0)
No	15 526 (38.2)	82 (58.6)	9 (4.9)	729 (45.8)	1113 (29.9)
Smoking					
<20 pack-years	13 615 (33.5)	48 (34.3)	56 (30.6)	507 (31.9)	1391 (37.4)
≥20 pack-years	26 368 (64.9)	91 (65.0)	119 (65.0)	1063 (66.8)	2274 (61.1)
Fagerström 1–6 points	29 264 (72.0)	102 (72.9)	124 (67.8)	1139 (71.6)	2600 (69.9)
Fagerström 7–10 points	11 142 (27.4)	38 (27.1)	56 (30.6)	445 (28.0)	1093 (29.4)
<20 cigarettes per day	17 230 (42.4)	53 (37.9)	82 (44.8)	725 (45.5)	1528 (41.1)
≥20 cigarettes per day	22 950 (56.5)	87 (62.1)	96 (52.5)	867 (54.5)	2155 (57.9)
Heavy smokers (based on pack-years, Fagerström scores and daily consumption levels)					
No	9845 (24.2)	30 (21.4)	46 (25.1)	356 (22.4)	988 (26.6)
Yes	30 591 (75.3)	109 (77.9)	135 (73.8)	1213 (76.2)	2711 (72.9)
Compliance with programme (based on attendance)					
Not compliant	14 479 (35.6)	44 (31.4)	1 (0.6)	691 (43.4)	1064 (28.6)
Compliant	25 731 (63.3)	89 (63.6)	182 (99.4)	825 (51.8)	2470 (66.4)
Living with a smoker					
No	25 802 (63.5)	101 (72.1)	120 (65.6)	1117 (70.2)	2316 (62.2)
Yes	14 410 (35.5)	38 (27.1)	61 (33.3)	451 (28.3)	1358 (36.5)
Living with others†					
Living alone	8754 (21.5)	52 (37.1)	—	656 (41.2)	744 (20.0)
Living with children (±adults)	7717 (19.0)	38 (27.1)	—	365 (22.9)	744 (20.0)
Living with adults (no children)	8436 (20.8)	49 (35.0)	—	543 (34.1)	692 (18.6)
Housing situation†					
Residential property	11 811 (29.1)	63 (45.0)	—	556 (34.9)	844 (22.7)
Cooperative dwelling	2172 (5.3)	6 (4.3)	—	139 (8.7)	184 (4.9)
Rented accommodation	10 464 (25.7)	64 (45.7)	—	828 (52.0)	1070 (28.8)
Other housing	248 (0.6)	4 (2.9)	—	34 (2.1)	62 (1.7)
Referral					
No	16 509 (40.6)	35 (25.0)	82 (44.8)	459 (28.8)	1544 (41.5)
Yes, from healthcare personal	18 927 (46.6)	100 (71.4)	53 (29.0)	1069 (67.2)	1770 (47.6)

Continued

**Table 1** Continued

	GSP n (%)	Health promotion counselling n (%)	Crash courses n (%)	Come & Quit n (%)	Other n (%)
Yes, from others	4047 (10.0)	–	48 (26.2)	–	305 (8.2)
Attempts to quit					
No previous attempts	12 258 (30.2)	55 (39.3)	38 (20.8)	565 (35.5)	1121 (30.1)
1–3 previous attempts	20 605 (50.7)	74 (52.9)	85 (46.5)	813 (51.1)	1835 (49.3)
>3 previous attempts	5526 (13.6)	11 (7.9)	38 (20.8)	178 (11.2)	543 (14.6)
Yes unknown number of attempts	1397 (3.4)	–	20 (10.9)	–	137 (3.7)
Smoking cessation clinic Setting					
Publicly oriented‡	31 008 (76.3)	91 (65.0)	97 (53.0)	1592 (100)	1780 (47.8)
Hospital (including midwives)	8198 (20.2)	17 (12.1)	82 (44.8)	0	1415 (38.0)
Other	1445 (3.6)	32 (22.9)	4 (2.2)	0	526 (14.1)
Geographic area					
Capital Region of Denmark	13 353 (32.9)	23 (16.4)	69 (37.7)	368 (23.1)	1845 (49.6)
Region Zealand	5856 (14.4)	4 (2.9)	78 (42.6)	131 (8.2)	248 (6.7)
Region of Southern Denmark	10 378 (25.5)	27 (19.3)	17 (9.3)	318 (20.0)	601 (16.2)
Central Denmark Region	9237 (22.7)	80 (57.1)	16 (8.7)	569 (35.7)	868 (23.3)
North Denmark Region	1827 (4.5)	6 (4.3)	3 (1.6)	206 (12.9)	159 (4.3)
Smoking cessation intervention Programme format					
Individual	5878 (14.5)	127 (90.7)	28 (15.3)	166 (10.4)	1707 (45.9)
Group	34 773 (85.5)	13 (9.3)	155 (84.7)	1426 (89.6)	2014 (54.1)
Target audience					
Patients and relations	3647 (9.0)	31 (22.1)	20 (10.9)	44 (2.8)	978 (26.3)
Employees (workplace course)	10 060 (24.8)	4 (2.9)	44 (24.0)	76 (4.8)	649 (17.4)
Ordinary citizens	22 132 (54.4)	71 (50.7)	107 (58.5)	1259 (79.1)	1386 (37.3)
Mixed	2516 (6.2)	1 (0.7)	6 (3.3)	76 (4.8)	84 (2.3)
Pregnant women (and partners)	1156 (2.8)	2 (1.4)	4 (2.2)	4 (0.3)	80 (2.2)
Other	1125 (2.8)	31 (22.1)	2 (1.1)	133 (8.4)	543 (14.6)
Medication offered for free					
No free medication	15 324 (37.7)	120 (85.7)	60 (32.8)	1342 (84.3)	1641 (44.1)
Free for days (<1 week)	17 367 (42.7)	8 (5.7)	97 (53.0)	39 (2.5)	880 (23.7)
Free for ≥1 week	4843 (11.9)	12 (8.6)	26 (14.2)	205 (12.9)	976 (26.2)
Counselling free of charge					
Yes	36 544 (89.9)	137 (97.9)	183 (100)	1589 (99.8)	3318 (89.2)
No	4066 (10.0)	3 (2.1)	0	0	400 (10.8)
Planned relapse prevention†					
No	13 413 (33.0)	58 (41.4)	–	945 (59.4)	898 (24.1)
Yes	11 751 (28.9)	82 (58.6)	–	647 (40.6)	1308 (35.2)

Dashes indicate that the variable was not measured

\*Owing to missing values, not all variables add up to the total number (and 100%).

†Data obtained from 2006 and to the present.

‡Covers interventions in the municipalities and pharmacies.

GSP, Gold Standard Programme.

## Statistical analyses

Results are reported as absolute numbers and percentages, including missing data, loss to follow-up and non-respondent analyses according to the RECORD guidelines<sup>20</sup> for population and clinical databases (base case). To compare these data to randomised controlled trials, the results were also reported according to the Russell Standards,<sup>21</sup> whereby non-respondents were presumed to have relapsed (worst case).

ORs were estimated using logistic regression analyses for men and women separately to test for differences in continuous abstinence levels. Initial analyses included selected prognostic factors from [table 1](#) adjusted for sex and age. Hereafter, the multivariable mixed-effect regression model for clustered data was fitted, and predictors were included based on the initial analyses and established knowledge. The final analyses were adjusted for the time of data collection, geographic regions, age,

being a disadvantaged smoker, heavy smoking, compliance, living with a smoker, setting, individual or group format, and supportive medication offered for free, and all predictors were entered together. Patients with missing values were excluded from the analyses. A multi-variable analysis was also performed for all patients together to obtain the OR for women compared with that for men. Statistically significant predictors of continuous abstinence were identified. The results are displayed as OR values and as corresponding 95% CIs. Non-respondent analyses were performed using a  $\chi^2$  test to compare respondents with non-respondents; compliant patients with non-compliant patients and patients who were intentionally not followed up with followed up patients according to the characteristics listed in [table 1](#).

A two-sided p value of <0.05 was considered statistically significant. All statistical calculations were performed using Stata/IC V.14 (StataCorp LP).

### Data access and cleaning

In this study, we had full access to the entire SCDB population. All Civil Registration System (CPR) numbers (CPR; a unique 10-digit number including the date of birth and sex assigned to every Dane at birth or to immigrants) were checked according to official validation rules. Invalid CPRs were corrected according to the Civil Registration System.<sup>22</sup> Age and sex were corrected accordingly.

Data from 2001 to 2005 were checked manually prior to registration. Questionnaires with missing or invalid data were returned to the smoking cessation units with instructions on how to correct the data. In 2006, data validation rules were established in the online registration application. Dates were validated to avoid non-excising dates, and rules were applied to ensure that required data were entered.

### Multiple quit attempts

It was possible for patients to enrol repeatedly and to thereby be registered in the database with two (or more) different entries specifying the intervention, baseline data and a follow-up for each intervention.

Owing to the collection of the CPR, it was possible to identify patients who had multiple interventions from 2006 to 2013. Before 2006, this was not possible. Patients

participating in multiple interventions were therefore not excluded from either period.

The extent of duplicates for the 29 102 patients from 2006 to 2013 was 1607 corresponding to 6.6% of the entries. We assumed that this value was similar before 2006 and take this into account in our interpretation of the findings.

## RESULTS

This study initially included 46 287 patients. Subsequently 12 052 (26%) patients were lost to follow-up, and 34 235 patients were included in the analyses. This number of missing values was considered small (0–5%), except for free supportive medication, which was 7.2%. The characteristics are given in [table 1](#).

Overall, 33% (11 184) of the responding patients reported being continuously abstinent after 6 months. If the non-respondents were considered to be smokers, this proportion was 24%. Crude quit rates by intervention type and sex are shown in [table 2](#).

### Predictors of abstinence

In the fully adjusted model, women were significantly less likely to remain abstinent than men (17% (OR=0.83, 95% CI 0.79 to 0.87)).

The GSP was the only intervention to present significant outcomes for men and women ([table 3](#)).

Though applying to very few patients, health promotion counselling seemed to be the most effective intervention for men (OR=2.64; 1.21 to 5.72), followed by the GSP (OR=1.69; 1.27 to 2.24) and other interventions (OR=1.50; 1.09 to 2.06). The effect of crash courses was not significant for men. For women, only the GSP increased the effect significantly (OR=1.31; 1.03 to 1.68).

For men and women, programme compliance was the most pronounced predictor of success, and more advanced age and not being disadvantaged or a heavy smoker were other predictors (see [table 3](#)).

An effect of the time of data collection was present, and the likelihood of remaining continuously abstinent for 6 months was slightly higher at the start of the data collection period (data not shown).

**Table 2** Continuous abstinence after 6 months by smoking cessation intervention not adjusted for participant characteristics

Smoking cessation intervention	Base case (RECORD criteria <sup>20</sup> )				Worst case (Russell criteria <sup>21</sup> )			
	All		Men	Women	All		Men	Women
	n	Per cent			n	Per cent		
Come & Quit	960	22.5	21.7	23.0	1592	13.6	14.1	13.3
Gold Standard Programme	30 400	32.8	35.0	31.5	40 651	24.5	26.1	23.6
Health promotion counselling	71	32.9	47.4	17.1	140	17.1	25.4	8.7
Crash courses	159	27.7	36.4	21.5	183	24.0	32.0	18.5
Other	2645	34.8	35.9	34.1	3721	24.8	25.3	24.4

The worst case counted the non-respondents as smokers.

**Table 3** Explanatory variables included in the final multivariable logistic regression analyses.

	Multivariable analyses OR (95% CI) Men n=11 724	Multivariable analyses OR (95% CI) Women n=18 184	Interaction with sex p Value
Smoking cessation intervention			
Come & Quit	1	1	
Gold Standard Programme	1.69 (1.27 to 2.24)	1.31 (1.03 to 1.68)	0.079
Health promotion counselling	2.64 (1.21 to 5.72)	0.48 (0.17 to 1.34)	0.013*
Crash courses	1.08 (0.58 to 2.02)	0.49 (0.28 to 0.87)	0.054
Other	1.50 (1.09 to 2.06)	1.20 (0.91 to 1.58)	0.244
<i>Participants</i>			
Age (years)			
15–24 years	1	1	
25–34 years	1.22 (0.91 to 1.62)	1.29 (1.06 to 1.57)	0.918
35–44 years	1.37 (1.04 to 1.80)	1.28 (1.06 to 1.55)	0.413
45–54 years	1.49 (1.14 to 1.96)	1.31 (1.08 to 1.57)	0.193
55+ years	1.48 (1.13 to 1.94)	1.35 (1.12 to 1.63)	0.337
Disadvantaged smokers†			
No	1	1	
Yes	0.81 (0.73 to 0.89)	0.82 (0.76 to 0.89)	0.594
Heavy smokers‡			
No	1	1	
Yes	0.73 (0.65 to 0.81)	0.65 (0.60 to 0.70)	0.021*
Compliance with programme§			
No	1	1	
Yes	3.65 (3.29 to 4.04)	3.58 (3.30 to 3.89)	0.430
Living with a smoker			
No	1	1	
Yes	0.94 (0.86 to 1.02)	0.92 (0.86 to 0.99)	0.590
<i>Smoking cessation clinic</i>			
Setting			
Citizen aimed	1	1	
Hospital (including midwives)	1.02 (0.85 to 1.21)	1.09 (0.94 to 1.27)	0.982
Other	1.13 (0.89 to 1.45)	1.05 (0.84 to 1.31)	0.191
<i>Smoking cessation intervention</i>			
Programme format			
Individual	1	1	
Group	0.96 (0.84 to 1.10)	0.97 (0.87 to 1.08)	0.696
Medication offered for free			
No free medication	1	1	
Free for days (<1 week)	0.87 (0.78 to 0.97)	0.87 (0.80 to 0.96)	0.199
Free for ≥1 week	0.97 (0.82 to 1.14)	0.95 (0.83 to 1.10)	0.163
Hierarchical cluster	Variance (95% CI)	Variance (95% CI)	
Smoking cessation clinic			
Variance of random intercepts	0.06 (0.04 to 0.11)	0.07 (0.04 to 0.11)	

In addition, the model was also adjusted for the time of data collection and for geographic regions. Statistically significant results are marked with an \*.

†Disadvantaged smokers: unemployed and receiving unemployment benefits and/or low education (no education except primary schooling and/or only short work-related courses).<sup>13</sup>

‡Heavy smokers: smoking ≥20 pack-years and/or daily consumption of ≥20 cigarettes and/or Fagerström nicotine dependency score of ≥7 points.<sup>12 19</sup>

§Compliance with the programme was defined as having attended at least 75% of the scheduled meetings<sup>17</sup> or for Come & Quit at least four sessions.<sup>8</sup>

### Non-respondent analyses

We performed a non-respondent analysis of the 46 287 smokers included in the study by comparing respondents (34 235 smokers) with non-respondents (12 052 smokers lost to follow-up). Respondents and non-respondents were significantly different in regard to every variable tested (see online supplementary appendix). The largest

difference between the two groups (16.8 percentage points) was seen in regard to compliance, where the smokers lost to follow-up were less likely to be compliant with the programme. In addition, time of data collection, age, education, employment, pack-years, housing situation, setting, geographic area and planned relapse prevention differed by more than 5 percentage points.



Another analysis performed on 82 387 smokers comparing patients not wanting to be contacted or who were intentionally not followed up (36 100 smokers) with those who were (46 287 smokers) showed differences of up to 8.4 percentage points (see online supplementary appendix). The largest difference was geographic area, but time of collection, and planned relapse prevention also differed by more than 5 percentage points between the compared groups.

## DISCUSSION

Overall, every third GSP intervention resulted in a successful outcome after 6 months. Compared with women, men were more successful, with an additional one in six patients being continuously abstinent. Only the GSP showed a significant result regardless of sex even after adjusting for independent variables affecting the outcomes.

Interestingly, the short interventions seemed to be highly effective for men, while women halved their odds of success following short interventions. For both sexes, compliance, as well as advanced age and not being a disadvantaged or a heavy smoker were predictors of successful quitting.

The high effectiveness of the GSP for men and women in our study was also observed in randomised and controlled trials evaluating the programme against typical treatments.<sup>23 24</sup> A review found intensive group interventions to be the most effective compared with other formats.<sup>25</sup>

Compliance was the most important predictor, increasing the odds of abstinence more than 3.5-fold regardless of sex. An earlier study showed a dose-dependent response between compliance and continuous abstinence for GSP; the more sessions attended, the greater the chance of succeeding.<sup>17</sup> It should be noted that compliant patients included in our study had several characteristics that were associated with high quit rates.

In line with other studies, we found that even though women were more likely to attend a smoking cessation intervention, they were significantly less likely to succeed than men.<sup>25 26</sup> Bohadana *et al.*<sup>27</sup> also confirmed these findings, which could be explained by differences in nicotine and behavioural dependence between women and men. Other studies have found no differences in regard to sex<sup>28 29</sup> or that women are more likely to quit smoking.<sup>30</sup>

Though only a few patients undertook short programmes, men showed more promising results, while women showed significantly worse results. Brief interventions are generally recommended, though their overall effect is low. In addition, the setting could be of relevance, as a recent review found no effect of short interventions among surgical patients.<sup>31</sup>

Interestingly, offering free nicotine replacement therapy (NRT) or other supportive medicine had a negative effect on outcomes. The literature is

contradictory on this matter. A recent study from England showed no effect of free NRT in combination with a supportive quit line for patients who wanted to quit.<sup>32</sup> In contrast, another study found that offering free NRT increased the chances of success significantly.<sup>33</sup> A possible explanation could be the influence of other non-individual variables, such as the type of health system, local general dental practices or the availability of over-the-counter drugs. Further studies are needed to clarify which group of smokers under which conditions would benefit from free NRT.

During the study period from 2001 to 2013, smoking prevalence in Denmark dropped from 30% to 17% daily smokers, corresponding to 1230–780 000 people. Over this period, 82 431 smokers aged 15 years or older received a face-to-face smoking cessation intervention programme registered in the SCDB, corresponding to ~7–11% of all daily smokers. Converted to a yearly basis, fewer than 1% of the smokers in Denmark have received a face-to-face smoking cessation intervention. This number is very low compared with that of England, where 5–10% of the smokers are treated by the Stop Smoking Service,<sup>29</sup> as well as compared with national and international guidelines recommending that 5% of all smokers should receive a smoking cessation intervention yearly. It is difficult to compare the present data to other countries since, to the best of our knowledge, no other countries have clinical registers with national coverage.

This study has limitations as well as strengths. The non-respondent analyses showed that the respondents were more compliant, indicating that the respondents were more likely to be continuously abstinent. Therefore, the results based on the RECORD criteria may overestimate the quit rate when extrapolated to non-respondents. In contrast, the compliance of patients with and without intended follow-up was more similar. Some of the differences identified could be attributed to the large sample size. The follow-up rate was relatively high (74%), and the large number of patients from across the country and across settings was a strength of this study. Even though the coverage was high, the SCDB may not cover all activities. However, only 3 of the 98 municipalities never reported to the database. Smoking cessation intervention activities across regions of Denmark differed more than the distribution of smokers.<sup>34</sup> Relatively, the North Denmark Region treated fewer smokers, while the Capital Region of Denmark treated more patients than expected based on the number of smokers in each region. However, even the most active region has treated only 0.6% of all smokers annually which is far lower than the recommended 5%.<sup>35</sup> An additional strength was the low amount of missing data. We addressed missing data according to RECORD guidelines.<sup>20</sup> Some of the programmes were only recorded in the database in a limited part of the study period. Two of the programmes only had a very low number of participants (0.3% and

0.4%) and the influence on the overall result is therefore very limited. The programme Come & Quit was established in 2011 but includes 3.4% of the smokers and may potentially affect the comparative analyses. However, time for data collection only showed a minor reduction of successful quitting overtime. Thus, the effect of the crash courses recorded only in the beginning of the period may be slightly overestimated. We also reported continuous abstinence as the primary outcome, in contrast to point prevalence, which has several limitations.<sup>36</sup> The self-reporting was a limitation, as patients are likely to overestimate their success by 3–6% compared with co-validated outcomes.<sup>37–39</sup> We had no reason to assume that this overestimation was unevenly distributed among the different interventions. Therefore, the groups should be comparable, even though the quit rates may be slightly overestimated in general. Owing to different cultural traditions, smoking habits and socioeconomic conditions, generalisations should be considered carefully. The implications of using the routinely collected health data from the SCDB in this study must be considered minimal, as the study is in line with the purposes of the database. Only minor changes in data collection took place over time to include new supportive medicine, and the eligibility has changed over time due to changes in the Danish health-care system.<sup>16</sup> We consider the completeness and precision of the data to be high.<sup>8</sup> We are not able to identify possible misclassifications, but we expect their occurrence to be very low. We are also aware of other potential confounders such as genetic predisposition, comorbidities, competing addictions and lifestyle factors that are not included in the analysis due to a lack of information.

From a societal perspective, it is highly interesting that the GSP is effective across different socioeconomic groups. A systematic implementation of the GSP would therefore be highly effective among lower socioeconomic groups with the highest smoking prevalence. Only by collecting nationwide data in a clinical database such as the SCDB it is possible to document this important effect. Furthermore, free NRTs, other supportive medications and self-payment counselling did not show any association with the quit rate, in agreement with a recent publication on financial incentives for smoking cessation.<sup>40</sup>

This study has raised a new hypothesis on the effectiveness of short interventions among men that should be investigated further.

Another area requiring further investigation is the effectiveness of smoking cessation among groups with very high smoking prevalence, such as mentally ill patients. Recent research indicates that smoking is associated with the development of psychosis because psychosis develops earlier and more frequently among smokers than among non-smokers.<sup>41</sup> The high prevalence of smoking among psychiatric patients has traditionally been interpreted as a form of self-medication, but this has now been questioned by a meta-analysis showing that

smoking cessation improves the mental conditions of smokers with and without a psychiatric diagnosis.<sup>42</sup>

A final area of major interest is that smoking cessation databases can be used for early detection, that is, to follow the effects of smoking cessation interventions across a country rather than waiting to see the effect directly on smoking-related illness and death. We recommend that other countries establish national smoking cessation databases for these purposes and for comparing effects between countries.

## CONCLUSION

Over time, Danish smoking cessation interventions have been shown to be effective in real life. Ultimately, one in three smokers are still abstinent at 6 months of follow-up (or one in four if non-respondents are judged as smokers). Compliance is the main predictor of successful quitting. We expected to find that the GSP would be the most effective intervention, but interestingly, short programmes also seem to have relatively strong effect among men, though the absolute numbers are very small. Only the comprehensive standard programme in Denmark, the GSP, works across sexes.

## Author affiliations

<sup>1</sup>WHO-CC Clinical Health Promotion Centre, Bispebjerg and Frederiksberg Hospital, Part of Copenhagen University Hospital, Frederiksberg, Denmark

<sup>2</sup>Tobacco Control Unit, Institut Català d'Oncologia (ICO-IDIBELL), L'Hospitalet de Llobregat, Barcelona, Spain

<sup>3</sup>Department of Clinical Sciences, School of Medicine, Universitat de Barcelona, Barcelona, Spain

<sup>4</sup>Health Science, University of Southern Denmark, Odense, Denmark

<sup>5</sup>WHO-CC Clinical Health Promotion Centre, Department of Health Sciences, Lund University, Skåne University Hospital, Malmö, Sweden

**Twitter** Follow Mette Rasmussen @mettemyr

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**Data sharing statement** Data from the SCDB are archived in the Danish Data Archive. Project descriptions, anonymised data sets and statistical codes used in this study are available from the corresponding author.

All authors, external and internal, had full access to all of the study data (including statistical reports and tables) and take responsibility for the integrity of the data and for the accuracy of the data analysis.

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Mette Rasmussen, Esteve Fernández and Hanne Tønnesen

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